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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,453	12/19/2005	Mehmet Toner	50254/005002	8260

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CLARK & ELBING LLP
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BOSTON, MA 02110

EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

MAIL DATE	DELIVERY MODE
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07/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,453	TONER ET AL.	
	Examiner	Art Unit	
	Deborah K. Ware	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16,17,24,25,27,44-46,48-50,70-89 and 117-130 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16,17,24,25,27,44-46,48-50,70-89 and 117-130 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 16-17, 24-25, 27, 44-46 and 48-50, 70-89, and 117-130 are pending.

Response to Amendment

The amendment filed April 16, 2007, was received and entered.

Election/Restriction Withdrawn

Applicant's amendments filed April 16, 2007, remove the requirement for restriction because all of the claims have been changed to the elected invention of record. Hence the restriction requirement has been removed because all claims are drawn to the same invention.

Claims 16-17, 24-25, 27, 44-46 and 48-50, 70-89 and 117-130 are examined on the merits.

Information Disclosure Statement

The information disclosure statements (IDSs) submitted on April 16, 2007 and July 2, 2007, were received. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-17, 24-25, 27, 44-46 and 48-50, 70-89, and 117-130 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly

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point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are rendered vague and indefinite because the claims do not appear to accurately describe the invention in clear and distinct terms. Examiners, therefore, suggest that claim 44 should require the type of process as follows. a cell population enriched in a first type of cell, that the first step (i) should require contacting a blood sample with a first microfluidic device comprising obstacles that form microchannels to accomplish cell separation as claimed by separating adult enucleated red blood cells from smaller cells than adult cells as a result of the smaller cells passing through the microchannels and the adult cells not passing through the microchannels in order to produce a fraction containing the adult enucleated red blood cells. Then in step (ii) contacting the fraction containing the adult enucleated red blood cells with a second microfluidic device comprising the obstacles that preferentially bind the first type of cell to provide a sample enriched in the first type of cell.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-17, 24-25, 27, 44-46 and 48-50, 70-89, and 117-130 are rejected under 35 U.S.C. 103(a) as obvious over Spence et al (US2002/0005354A1), cited on previously enclosed PTO-892 Form, in view of newly cited Chou et al, cited on enclosed PTO-892 Form.

Claims are drawn to method of producing a cell population enriched in a first cell type comprising subjecting blood sample to separation comprising contact with a microfluidic channel comprising obstacles so that smaller cells are directed in one direction and larger cells are directed in another second direction and separation comprising contact with the device to produce an enriched cell population.

Spence et al teach a method of producing a cell population enriched in a first cell type, note page 3, column 1, line 4, and page 5, column 2, [0054], line 15 and page 8, column 1, [0078] lines 1-2 and column 2, [0082], all lines. The microfluidic device is disclosed.

Chou et al teach the obstacles to be pillars, note figure 1, of page 12, wherein support pillars are used to support the microfluidic device channels.

The claims differ from Spence in that obstacles as pillars are not clearly disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of Spence et al and Chou et al, as cited above to provide for a method for producing an enriched cell population via cell-based size separation or cell-binding separation using a microfluidic device having obstacles as pillars as clearly disclosed by the combination of Spence et al and Chou et al, respectively. Spence et al do teach that cells so separated are separated according to predetermined characteristics of which size based separation and/or cell binding based separation is/are obvious modification(s) of the cited prior art. An obstacle at which separation occurs is noted in Figure 6. Also the secondary reference of Chou et al clearly teach the obstacle to include raised pillars as required by the instant claims. Furthermore, the cells, such as red blood cells, which are disclosed and so being separated can flow in different directions as they are separated.

Further, the blood cells can be human which includes fetal blood cells. The percentage of cells which can selectively bind can be accurately controlled by the microprocessor disclosed to be on the chip of the reference. Also the two dimensional array is disclosed by the reference since there is more than one channel. Further, the direction is disclosed to be reversible and so the property of preferential reversible binding is an intrinsic feature of the disclosed chip.

In addition, the reference discloses a window at page 8, [0081], line 5, which can intrinsically function to serve as a field for actuating preferential binding as necessary. It would have been obvious to design the program of the disclosed device to provide for 60% of the first type and 70% of cells of the second type, and further to provide for a binding moiety to control flow in a two-dimensional array and to separate the cells based upon size and/or their binding capabilities. Also to select for a fetal cell is clearly within the guidance of the description of the cited reference. The claims are suggested if not disclosed by the cited prior art and are prima facie obvious over the cited prior art.

Response to Arguments

Applicant's arguments filed April 16, 2007, have been fully considered but they are not persuasive. Contrary to Applicants' argument that Spence et al do not teach size based separation and/or cell binding separation, they do at least suggest that these among many other cell characteristics may be selected for separation of the cells. While Spence et al do teach a detectable signal as well, Applicants' claims do not necessarily omit a separation of cells based upon detectable signal, and such signals can be cell size and binding characteristics. The obstacles disclosed by Spence et al and Chou et al will intrinsically function as means for cell separation because they are present in the microfluidic device. The point that the detection window examines each cell individually is noted, however, each cell having a different size can be examined individually if one of skill in the art would desire to do so, but the presence of the window disclosed does not necessarily take away the intrinsic function of the disclosed obstacles. Chou et al clearly teaches that the presence of the obstacles provides an

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improvement to the microfluidic device and Spence et al clearly teach that the cells are enriched. Thus, one of skill would have been motivated by the cited prior art to provide for obstacles to enrich cells via cell based binding separation or cell size based separation. The claims are suggested by the cited prior art.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


DEBORAH K. WARE
PATENT EXAMINER

Deborah K. Ware
July 7, 2007